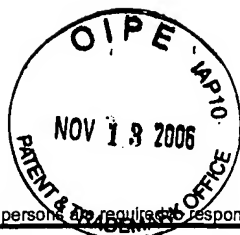


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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MAXC:014US

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on November 6, 2006

Signature Michael C. Barrett

Typed or printed name Michael C. Barrett

Application Number

10/675,592

Filed

September 30, 2003

First Named Inventor

Sergey Dzekunov

Art Unit

1615

Examiner

Fernandez, Susan Emily

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 44,523

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Michael C. Barrett

Signature

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512-536-3018

Telephone number

November 6, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Arguments in Support of Pre-Appeal Brief Request for Review for 10/675,592

I. The Indefiniteness Rejection Should be Withdrawn

The Office asserts that claims 1-16 are rendered indefinite by use of the phrase “substantially constant” in independent claims 1 and 7. According to the Office, “it is not clear exactly how much variation is allowable for an electric field to be considered ‘substantially constant’ or exactly what values are considered out of the scope of that term.” The final Office Action mailed July 5, 2006 (“The Action”) at p. 2.

Applicants disagree that the phrase “substantially constant” renders the present claims indefinite. The Office is applying a standard for definiteness that has been expressly rejected by the Federal Circuit. *See Verve LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119-1120 (Fed. Cir. 2002); *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821-22 (Fed. Cir. 1988). In *Verve*, the court considered whether use of the phrase “substantially constant wall thickness” rendered a claim indefinite. Although there was no specific definition for “substantially constant” in the specification, the Federal Circuit reversed the district court’s holding of indefiniteness, stating that “[t]he question is **not** whether the word ‘substantially’ has a **fixed meaning** as applied to ‘constant wall thickness,’ but how the phrase would be understood by persons experienced in this field of mechanics, upon reading the patent documents.” *Id.* (emphasis added). The court went on to state that:

[i]t is well established that when the term ‘substantially’ serves reasonably to describe the subject matter so that its scope would be understood by persons in the field of the invention, **and to distinguish the claimed subject matter from the prior art**, it is not indefinite.

Id. at 1120 (emphasis added).

As the Federal Circuit made clear in *Verve* and *Andrew*, there is no requirement that it be clear “exactly how much variance is allowable” or “exactly what values are considered” for

every parameter recited in a patent claim. Applicants are entitled to use terms of degree such as “substantially” to “avoid a strict numerical boundary to [a] specified parameter.” *Verve*, 311 F.3d at 1120. “Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.” *Andrew*, 847 F.2d at 822 (quoting MPEP).

Persons of ordinary skill in the art would understand from the present specification that the term “substantially constant magnitude” is a term of degree that is used to distinguish the electric field used in the present method from the electric field used in “conventional techniques in which the duration of an electrical pulse (or pulses) applied to electrodes primarily determines the exposure of the sample to an electric field.” The Specification at 12. Additionally, the Specification provides guidelines concerning “substantially” at page 10, line 28-page 11, line 2. The phrase “substantially constant” does not render the claims indefinite. *See Verve*, 311 F.3d at 1120; *Andrew*, 847 F.2d at 821. Accordingly, Applicants respectfully request removal of the present indefiniteness rejection.

II. The Anticipation Rejection Should be Withdrawn

The Office’s rejection of claims 1-3, 7-8, and 11 as anticipated by Muller relies on the same flawed interpretation of “substantially constant” the Office has applied in the indefiniteness rejection discussed above. While Applicants have relied, in part, on the “substantially constant magnitude” element of the present claims as a means of distinguishing them over the cited art, the Office asserts that “substantially constant” is “open to interpretation,” and thus the Office apparently affords the term no patentable weight.

As explained above, persons of ordinary skill in the art would understand from the Specification that the term “substantially constant magnitude” is a term of degree that is used to

distinguish the electric field used in the present method from the electric field used in “conventional techniques in which the duration of an electrical pulse (or pulses) applied to electrodes primarily determines the exposure of the sample to an electric field.” The Specification at 12.

Muller is directed to the conventional types of pulsing that are explicitly distinguished by the claims and the Specification. *See* Muller’s ‘175 patent at col. 1, line 19 (“permeation by means of **short electrical pulses**”); col. 3, line 18 (“the electrodes (**pulse electrodes**) have field-forming devices); col. 3, lines 41-42 (“**electroporation pulse amplitudes**”); col. 4, lines 30-34 (confirming that the electroporation being discussed is conventional and stating “**permeation pulses** will not be explained in detail”); col. 5, line 33 (“**permeation pulses**”); col. 7, lines 36-38 (discussing “**pulse voltages**”); col. 8, lines 56-58 (“**Electroporation is based on the effect of a DC voltage pulse** on the object to be treated.”); col. 9, lines 4-5 (discussing DC “**voltage pulse**”) (emphases added). Muller nowhere discloses or even suggests using an electric field with a substantially constant magnitude, as presently claimed.

Moreover, Muller does not disclose using an electric field that is generated with electrodes that are continuously energized at least while a sample traverses the electric field, as recited by present claims 1 and 7. Persons of ordinary skill in the art would understand that the conventional types of pulsing taught by Muller are achieved by electrodes that are in an un-energized (*i.e.*, “OFF”) state prior to the pulse, an energized (*i.e.*, “ON”) state during the pulse, and then an un-energized state following the pulse. Whether the continuously energized electrodes of the present claims could theoretically generate a pulse, as the Office asserts at page 4 of the Action, is irrelevant to the issue of anticipation. What is relevant is what a person of

ordinary skill in the art would understand Muller to teach, and that person would not understand a teaching of conventional pulsing to be a teaching of electrodes that are continuously energized.

Furthermore, Muller does not teach that electroporation is effected by sample displacement, as recited by present claims 1 and 7. Muller appears to teach a method wherein an object is displaced, but it is not the displacement that leads to electroporation. The displacement in Muller only leads to the sample being held at a location, at which point a pulse is applied. *See* Muller at col. 5, lines 40-48 (stating that the sample is “**kept** there using dielectric forces” which “**hold** the objects in the electrode system”). No displacement appears to occur during the electroporation process; the electroporation results from the applied pulse, not the displacement. In contrast, claims 1 and 7 involve a displacement for effecting electroporation. *See* claim language; *see also* the non-limiting statement within the Specification at 12 (“[I]n streaming EP, the rate of relative motion between an electric field and a sample can be used to achieve electroporation **instead** of signal pulsing applied to the electrodes.”).

At least because Muller lacks disclosure of explicit elements of claims 1 and 7 as described above, there can be no anticipation of claims 1 and 7 or their dependent claims 2, 3, 8 and 11. Accordingly, Applicants respectfully request removal of the present anticipation rejection.

III. The Obviousness Rejection Should be Withdrawn

The Office’s rejection of claims 1-13 as obvious over Muller in view of Baumann or Acker relies on the same flawed interpretation of “substantially constant” the Office has applied in the indefiniteness rejection discussed above.

As explained above, Muller is directed to the conventional types of pulsing that are explicitly distinguished by the claims and the Specification. Muller nowhere discloses or

suggests using an electric field with a substantially constant magnitude. Muller also does not disclose or suggest using an electric field that is generated with electrodes that are continuously energized at least while a sample traverses the electric field, nor does Muller disclose or suggest effecting electroporation through sample displacement.

Baumann and Acker fail to fill the void in Muller's teaching. Baumann and Acker nowhere disclose or suggest using an electric field with a substantially constant magnitude. In fact, Acker (like Muller) is explicitly directed to the conventional types of pulsing distinguished by the claims and specification: "A capacitor network applies alternating positive and negative **pulses** of high voltage across the electrodes ... to electroporate the cells." Acker, Abstract. Furthermore, Baumann appears to teach against electroporation effected by displacement by disclosing that a cell to be electroporated should be "**immobilized**" and adhered to a support area during electroporation. Baumann, col. 10, line 67 - col. 11, line 1.

For at least these reasons—all the claim elements are not met, even upon combination—no *prima facie* case of obviousness can be established, and the claims are in condition for allowance. Applicants also point out that each of the cited references is drawn to different technological areas and purposes, and therefore there is no motivation to combine their elements. Even if a combination were or could be made, the principle of operation of the devices would likely be destroyed, and the Office has not provided any evidence concerning a reasonable expectation of success. Applicants respectfully request the withdrawal of the present obviousness rejection.